

§ 1.230

21 CFR Ch. I (4–1–11 Edition)

(iii) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

(14) *You or registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

PROCEDURES FOR REGISTRATION OF FOOD FACILITIES

§ 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, packs or holds food for consumption in the United States must register the facility no later than December 12, 2003. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must register before the facility begins such activities. An owner, operator, or agent in charge of a facility may authorize an individual to register the facility on its behalf.

§ 1.231 How and where do you register?

(a) *Electronic registration.* (1) To register electronically, you must register at <http://www.fda.gov/furls>, which is available for registration 24 hours a day, 7 days a week. This website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(3) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(4) You will be considered registered once FDA electronically transmits

your confirmation and registration number.

(b) *Registration by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (a) of this section, you may register by mail or fax.

(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD-ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Registration by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods

provided under paragraph (a) of this section, you may register by CD-ROM.

(1) Registrants submitting their registrations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) These files must be submitted on a portable document format (PDF) rendition of the registration form (Form 3537) and be accompanied by one signed copy of the certification statement that appears on the registration form (Form 3537).

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) A CD-ROM may contain registrations for as many facilities as needed up to the CD-ROM's capacity.

(5) The registration on the CD-ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the submitter unprocessed.

(8) FDA will enter CD-ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(11) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(d) *Fees.* No registration fee is required.

(e) *Language.* You must submit all registration information in the English

language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

[68 FR 58960, Oct. 10, 2003, as amended at 69 FR 29428, May 24, 2004; 73 FR 15883, Mar. 26, 2008]

§ 1.232 What information is required in the registration?

Each registrant must submit the following information through one of the methods described in § 1.231:

(a) The name, full address, and phone number of the facility;

(b) The name, address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(c) For domestic and foreign facilities, the names, addresses, and phone numbers of the owner, operator, and agent in charge.

(d) For a foreign facility, the name, address, phone number, and, if no emergency contact is designated under § 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent;

(e) For a domestic facility, an emergency contact phone number;

(f) All trade names the facility uses;

(g) Applicable food product categories as identified in § 170.3 of this chapter, unless you check either "most/all human food product categories," according to § 1.233(j), or "none of the above mandatory categories" because your facility manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

(h) The name, address, and phone number for the owner, operator, or agent in charge;

(i) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/